

JUL 5 2002



K02/253

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.  
1717 West Collins Avenue  
Orange, California 92867  
(714) 516-7484 - Phone  
(714) 516-7488 - Facsimile  
Colleen Boswell - Contact Person

Date Summary Prepared: April 2002

Device Name:

- Trade Name – *Ultrasonic Tips with Diamond Coating*
- Common Name – Ultrasonic Tips
- Classification Name – Ultrasonic Scaler, per 21 CFR § 872.4850

Devices for Which Substantial Equivalence is Claimed:

- Sybron Endo/Analytic, *Ultrasonic Tips*

Device Description:

The *Ultrasonic Tips with Diamond Coating* are utilized in endodontic root preparation procedures which includes retro-prep of root ends in order to make space for permanent filling material in the canal. The tips are composed of stainless steel with a layer of fine diamond particles.

Intended Use of the Device:

The intended use of the *Ultrasonic Tips with Diamond Coating* is for endodontic root preparation procedures which includes retro-prep of root ends in order to make space for permanent filling material in the canal.

Substantial Equivalence:

*Ultrasonic Tips with Diamond Coating* is substantially equivalent to other legally marketed devices in the United States. *Ultrasonic Tips with Diamond Coating* functions in a manner similar to and is intended for the same use as the *Ultrasonic Tips* marketed by Sybron Endo/Analytic.

1717 West Collins Avenue, Orange, CA 92867 800-537-7824 714-516-7400



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 5 2002

Sybron Endo/Analytic  
C/O Ms. Colleen Boswell  
Director, Corporate Compliance  
Sybron Dental Specialties, Incorporated  
1717 West Collins Avenue  
Orange, California 92867

Re: K021253

Trade/Device Name: Ultrasonic Tips with Diamond Coating  
Regulation Number: 872.4850  
Regulation Name: Ultrasonic Scaler  
Regulatory Class: II  
Product Code: ELC  
Dated: April 16, 2002  
Received: April 19, 2002

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

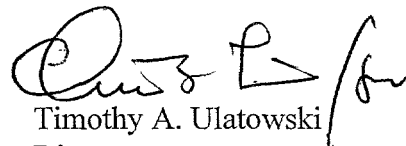
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski", with a stylized flourish at the end.

Timothy A. Ulatowski  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Sybron Endo/Analytic

510(k) Number (if known): K021253

Device Name: Ultrasonic Tips with Diamond Coating

Indications For Use:

The *Ultrasonic Tips with Diamond Coating* are utilized in endodontic root preparation procedures which includes retro-prep of root ends in order to make space for permanent filling material in the canal.

Susan Rynn  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K021253

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)  
(Optional Format 1-2-96)